MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

Ronald Reagan Building
International Trade Center
Horizon Ballroom
1300 13th Street, N.W.
Washington, D.C.

Friday, December 14, 2001
9:01 a.m.

COMMISSIONERS PRESENT:

GLENN M. HACKBARTH, Chair
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ALAN R. NELSON, M.D.
JOSEPH P. NEWHOUSE, Ph.D.
JANET G. NEWPORT
CAROL RAPHAEL
ALICE ROSENBLATT
JOHN W. ROWE, M.D.
DAVID A. SMITH
RAY A. STOWERS, D.O.
MARY K. WAKEFIELD, Ph.D.

Agenda item:
Paying for technologies in the prospective payment system for hospital outpatient department services
-- Chantal Worzala, Dan Zabinski

MR. HACKBARTH: The next item on the agenda is paying for technologies in the outpatient hospital PPS.

DR. WORZALA: Good morning. Today, Dan and I will be discussing how Medicare currently pays for technology in the outpatient PPS, alternatives for changing the payment mechanism, and possible draft recommendations for inclusion in the March 2002 report.

Congress was concerned that the 1996 data used to set payment rates in the outpatient PPS did not include the cost of newer technologies. Therefore, the BBRA mandated that supplemental payments be made when certain drugs, biologicals, and medical devices are used. That also includes radiopharmaceuticals. That additional payment, called a pass-through payment is meant to cover the incremental cost of the item.

Thus, for example, when a pacemaker is implanted the hospital receives the standard payment set for that service plus an additional amount calculated from the hospital's reported cost for the pacemaker if those costs are higher than the device costs already included in the standard payment. Hospitals receive pass-through payments for each eligible item for two to three years. After that the cost of these items are incorporated into the relative weights.

The provision is meant to be budget neutral with spending on pass-throughs limited to 2.5 percent of total payments. However, through administrative action and at the request of Congress, budget neutrality was not maintained in 2000 or 2001. We're a little bit uncertain at the moment about what will happen in 2002. The Administration has said that they will go ahead and implement the 2002 rates on January 1. However, the committees of jurisdiction did, in the last couple of days, send a letter to CMS requesting that they delay implementation until April 1. So we'll see how CMS responds to that letter.

If CMS does delay and pay on 2001 rates for the first three months of 2002, then the key difference is that the budget neutrality for the pass-through items would not be maintained for those three months. And in a final rule issued in early December, CMS announced that the pro rata reduction required to maintain budget neutrality would be 68.9 percent. So it's a

fairly significant difference in the payments for pass-through items depending on how CMS responds to the letter.

MR. HACKBARTH: Chantal, would there be any reprocessing of the claims? In other words, the ones that are paid in the first quarter under the 2001 rates, would that just be the amount that they're paid forever, or would there be an effort to go back and correct?

DR. WORZALA: They would go ahead and pay the 2001 rates and that would be it. That is one of the principal reasons for requesting the delay is that then there would be no need to either hold claims or reprocess claims.

Despite all this talk we do think that the size of the pro rata reduction in 2002 is a short term issue that should be resolved by the end of 2002 when eligibility for pass-through payments will end for many items. Consequently, we would like to focus your attention today on the systemic problems with the pass-through payments that we have identified previously, and alternative solutions to those problems.

In previous reports and comments on the August 2001 proposed rule MedPAC has identified a number of systemic problems with the pass-through payment mechanism. First, the payment mechanism provides incentives to raise prices and charges. This is because the pass-through payment amounts are determined based on average wholesale price for drugs and biologicals. However, we know that AWP generally exceeds acquisition cost and can be manipulated by manufacturers.

For medical devices, the pass-through payment amounts are determined based on hospital's charges reduced to cost using a predetermined cost to charge ratio that applies to outpatient services as a whole. Therefore, pass-through payments for devices can easily be increased by increasing charges for those services.

Second, providing a separate payment for certain technology gives hospitals an incentive to use pass-through items rather than comparable items that are bundled into the APC payment. This is due both to the potential for payments above cost resulting from the actual payment mechanism, and also because marginal payments will increase when those items are used. This is one of the reasons we moved to bundled payment systems because item-specific payments leads to increased use.

Third, the incorporation of excessive pass-through costs into the relative APCs at the end of the pass-through eligibility for a specific item may result in distortion of the relative weights. The pass-through cost data are used to modify the relative weights, and because recalibration of the relative

weights is done in a budget neutral manner, services that use pass-through items will have the relative weights increase while the relative weights of services that do not use pass-through items decrease.

This would be appropriate if the cost data collected through the pass-through payments were accurate. However, the incentive for overstated pass-through costs may well result in a distortion of the relative weights in favor of services that use new technologies. This also has a distributive effect among facilities to the extent that some hospitals are more likely than others to provide services that use the pass-through items.

We did see the effect of this in the fold-in that was in the final rule for 2002. The impact table does that the result of that fold-in would be a significant decrease in payments to rural hospitals and a significant increase in payments to urban hospitals, and especially large urban hospitals.

Just one more fact on that point, which is that small rural hospitals are still held harmless from losses on outpatient payments through 2003, so that that impact which shows the impact of the fold-in, is not the final payment impact. It's just the impact of that fold-in, and it will be at least partially offset by the hold harmless.

MR. MULLER: Chantal, if I could have a factual -- the discussion we had this month I thought went in a different direction so now I'm confused, because I thought that these were in fact pass-throughs so they were passed through to the supplier, and neither rural nor any other hospital in that sense received it. So you're telling me different this time? What did I misunderstand?

DR. WORZALA: This is the impact on relative weights of folding in costs from pass-through items into the base rate. So the impact that we're seeing on rural hospitals is the decrease in relative weights for APCs that do not have pass-through items. That's because rural hospitals are less likely to provide services for which there are pass-through payments.

MR. MULLER: That's a second order fact, that when they get reweighted hospitals that have a less-than-average utilization of these devices, their APCs get reweighted down. But my understanding was from last month's discussion that these are in fact pass-through payments. So when you use the word, there are incentives for doctors and hospitals to use it, wehther they're large or urban or specialists. I don't see where there are incentives for that. What am I missing? Why are there incentives if it's a pass-through?

DR. WORZALA: Why are there incentives if it's a pass-

through; that's really your question. There can be a difference, for example, on the device side between what a hospital charges versus what they pay for the item. So there is a potential there for some of the money to stay in the hospital. Similarly, for the drugs, the hospital is paid 95 percent of AWP and then the hospital turns around and presumably negotiates their prices for these drugs with the suppliers. So there is a potential for a difference between what the hospital is paid and what the hospital then pays manufacturers.

MR. MULLER: You have more microeconomists in your mind than I've ever seen in any hospitals.

MR. DEBUSK: Let's talk about affecting the small rural hospital. But what about that hospital that is not in that category, it's a small urban and small urban hospitals use very few pass-through codes that require C-coded products. What does it do to those hospitals?

DR. WORZALA: I would have to double-check the impact table for the exact number but they are significantly negatively affected.

In addition to the payment problems that were noted above, the pass-through creates two additional concerns. First, the special payments for certain items introduces an administrative burden for hospitals and CMS, both of which are already taxed with implementing a new payment system. Hospitals must code the pass-through item separately, and for devices determine which category to assign a particular item. CMS must process these additional codes and determine payments at the hospital level for medical devices.

In 2002, there are over 300 pass-through codes covering more than 1,000 pass-through items. In contrast, there are about 400 codes for actual outpatient services.

Second, the use of pass-through payments in the outpatient PPS creates an additional difference in payments for both services and new technologies across sites of care. This is an issue that MedPAC and CMS have struggled with over the years, and I think one of the reasons for establishing an outpatient PPS was to create a standard that could be used across sites of care, at least between outpatient PPS and ambulatory surgical centers. So there is an issue here of putting an additional difference into place.

That completes my summary of the problems with the pass-through mechanism. Dan will now discussion some options for changing the system.

DR. ZABINSKI: The flaws in the current system that Chantal just discussed suggest that an alternative system for paying

technology in outpatient departments may be appropriate. We have identified three possibilities. One option is for CMS to continue the pass-through but make some modifications. One of these modifications would be to base the pass-through payment on national rates that better reflect acquisition costs than the current cost-based payments.

Also, CMS should make pass-through payments accurately reflect the incremental costs of the pass-through items over the items they replace. Incremental costs are determined as the reported costs of the pass-through items minus the cost of the items being replaced in the applicable APC groups. But the cost of the items in the APCs may be under-represented, so the amount of the incremental cost calculated may be too high than the actual cost.

Finally, the pass-through system should exclude items whose costs are reflected in the data used to determine the base rates. Pass-through payments for these items are not necessary because the base rates already take their costs into account.

A second option we've considered is to remove all drugs, biologicals, and devices, both pass-through and non-pass-through, from the outpatient PPS and pay for them under a fee schedule. This is similar to the idea I just mentioned of setting national rates for pass-through technology, but in this case we would set payment rates for all technologies, not just the pass-through.

The potential advantage of unbundling all technology like that is a level playing field between pass-through and non-pass-through technology. If you only unbundle pass-through technology, that could give hospitals incentive to either use or avoid pass-through technology in relation to other technology because there would be a very different system between paying the two groups.

The final option is to phase out the pass-through payments and reimburse technology only through the base payment rates in the outpatient PPS. This option would work most effectively if CMS incorporated the new technology in the base rates quickly. This would require a timely system for introducing new codes for technology, collecting the data on their cost, and then incorporating those costs into the base rates.

Now all three of these options have the advantage that they would remove the incentives for hospitals and providers to increase prices for pass-through technology. Consequently, if we set rates appropriately in options one and two then all three of options would minimize distortions of relative weights in favor of services and providers that use pass-through technology.

But despite these mutual advantages of the three options

there are also some importance differences. On this slide here we have a table where in the first column we list the three options and the last two columns we indicate that the modified pass-through option and the fee schedule option would be much more burdensome on CMS and hospitals than the phase-out.

Also, setting appropriate rates for the first two options may be difficult for CMS. I base that assertion on a study by the General Accounting Office that indicates that CMS has not been successful in setting appropriate rates on the DME fee schedule for two reasons.

First, the classification codes that they use, the HCPC codes often encompass a broad range of products that have a wide price range. Second, the data that they available to set rates may not accurately reflect the market prices of the products. And the agency may face similar problems in setting rates for devices used in outpatient departments because many of them will be paid under the DME fee schedule if they were not being paid under the outpatient PPS.

Now the downside for a phase-out is in the second column of the last row. In particular, under a phase-out we may not pay adequately for high cost new technology, giving hospitals a financial incentive to avoid using them. This may be a weak incentive though because underpayments would first of all have a limited duration, lasting only until CMS has data to include the cost of the new technology in the base rates. Also the scope of the inadequate payments is expected to narrow because the number of pass-through items is expected to decrease substantially in 2003 and thereafter.

Finally, I think it's possible that this financial incentive would not significantly affect physician's use of new technologies in OPDs. The way I see it is that hospitals would have to influence which technologies physicians used and in what setting, and I'm not sure that they could be successful in taht regard on a large scale.

Now at this point I'll turn it over to the commissioners. I guess the idea is that we'd like to make a decision on which of these options is the most appropriate course of action. Then based on that decision we'll present the draft recommendation.

DR. WAKEFIELD: Chantal, I want to go back to some of the background that your provided. You had mentioned the hold harmless that's in place for small rural hospitals related to outpatient payment. I think part of the reason why that hold harmless was put into statute was because there was a sense that there needed to be some period of time to collect accurate and adequate data to reflect what was going on in rural hospitals in

terms of getting some -- just building as much accuracy into that payment system as possible.

So I guess what I'm asking is a question. A concern I've got is that with the pass-through, the data that are being collected are maybe putting us in a position where we're not going to have a number of years of very good data that serve as a platform to inform the accuracy once we've switched over, the first of January 2004, to shifting those small rural hospitals to APCs and lifting that hold harmless. So what we're seeing potentially is a continued depression of what rural hospitals are getting paid for outpatient, and we're trying to collect accurate data, then all of the sudden in 2004 we've lifted that hold harmless.

How accurate are the data in terms of reflecting other extraneous things like pass-through payments versus what's really going on in small rural hospitals outpatient services? Can you comment on that? It's tangentially related, but that informs my thinking about where ultimately we go here.

DR. WORZALA: Yes. I would characterize the hold harmless payments more as a transitional mechanism to protect hospitals that were perceived to be vulnerable. Impact analyses of the payment system did show that small rural hospitals in particular, and cancer hospitals in particular would be fairly negatively affected by the new payment system. So those provisions were put in place to give them, in the case of small rural hospitals, a transitional additional payment as they learn to cope, and also I guess to provide time to see how they're faring under the new PPS and see if they should continue to receive different payment; if they should have some sort of special payment provision.

So I don't know that it relates so much to this, but you are correct that the services that they provide, those payments for those services are negatively impacted, at least in a large scale, from the recalibration of relative weights.

In terms of data availability, we do haev a significant problem in taht CMS has not been able to provide claims data from operation under the outpatient PPS to date. This was due to a programming error that resulted in claims data that are not usable at this point in time. They plan to have a fix to that problem and data may be available in the spring. I do think that it's a significant problem that over a year after the payment system was implemented we don't have any data.

So I don't know that this pass-through mechanism really affects data availability. It's more the other issue that really affects data availability.

DR. WAKEFIELD: If I could just follow up, that's helpful to

know because I really thought that part of -- I'll go back and check this, too. I really thought that part of why that hold harmless was implemented was because the data that were available, that hospitals had been collecting, rural hospitals had been collecting and reporting were really inaccurate. There wasn't an incentive for them to provide accurate. So this provided a window knowing that, you're going to be transitioned over. You'd better be collecting accurate data so we've got a base to work from that's as precise as it can be.

Then my concern, if that was the case, that overlaid on top of that is what's happening as a result of what we're talking about today. So is it going to get them to the point where in fact their data are accurately reflecting what's going on in outpatient? But we can have that discussion offline and explore it further. But if that is the clear, and it clearly has implications I think beyond, perhaps beyond what you just described.

DR. WORZALA: Yes. Very quickly, in order to be paid under the outpatient PPS they do have to be coding claims accurately. So that does give them the incentive to code more accurately than in the past. So when and if the claims data become available it should be more uniformly coded across hospital types.

MR. MULLER: The original purpose of this policy, I take it, is to make sure the beneficiary gets the right services in the eyes of the Commission. In some ways I see this somewhat comparable to outlier policies where one wants to take into account, when there are extraordinary costs, that there not be a willingness to avoid the appropriate treatment just because the cost of several standard deviations outside normal costs.

So when we use words like level playing field and so forth, I think we should keep reminding ourselves the payment policy is not the end of the program. The payment policy is the servant of the programmatic goals. Therefore, we would want, as we look at our considerations here, to neither have clinicians and institutions misusing, overutilizing services because there's some kind of payment incentive. On the other hand, we don't want to just save by having just standard pricing. That appropriate items may be much more costly not be used.

So as I think about our alternatives here, if we're very much concerned about the kind of pricing -- one of the discussions we had last month is maybe go more for a fee schedule on some of these. But I would be hesitant to get into a system where we just totally move away from any kind of outlier payments and therefore avoid the use of the appropriate technology.

There's obviously a desire on the part of physician and

patient to use this technology that's beneficial to the beneficiary. So if we look at only avoiding some of the possible consequences of either AWC pricing and so forth, we don't want to go so far, therefore, to take away the incentive to use the right technology.

But I sometimes get a sense of -- and still being relatively new here -- the language we use here is very much a language where we focus so much on the incentives of payment and almost use that as a way of overriding appropriate clinical judgment. So I'm concerned that we use the language of clinical judgment as well the language of payment philosophy. It just kind of radiates a staff work we have that has kind of the payment policy as the end of the program.

MR. HACKBARTH: Can I ask a question related to this? In the case of outpatient services, Congress elected to do a pass-through for new technology to make sure that people weren't deprived of it. We don't use that approach on the inpatient side. What was the rationale for saying that we should deal with outpatient differently, and how valid is that, that rationale?

MR. MULLER: That's why I used the outlier example, and Mary and others can comment on that. In some sense, the outlier provisions allow for some of that in the inpatient side. It's not specifically addressed to that, but the outlier is meant to cover other things in addition to new technology. But it allows for a variety of factors to allow for special costs and cases.

MR. DEBUSK: May I take a shot?

DR. WORZALA: Excuse me, just one factual item. There is an outlier policy in addition in the outpatient PPS.

MR. DEBUSK: In the DRG, I think for new technology often times for the DRG they issue a new DRG to increase the payment for new technology, or improved technology.

MR. HACKBARTH: Doesn't the same mechanism exist for the outpatient PPS?

DR. WORZALA: Yes. On the inpatient side, some might say as a follow-on to the pass-through on the outpatient side, BIPA did introduce a similar mechanism on the inpatient side. It is different and one might say there was some learning that was done in that the inpatient pass-through legislation states that payments should be based on an average national price for the technology, and CMS is given the authority to set those prices. The mechanism has been described in regulation. It will become effective fiscal year 2003. It was meant to be this fiscal year but CMS concluded that they were not sufficiently prepared to implement it and decided to delay for a year.

DR. ROSS: But to answer your question, Glenn, the key

difference between the two systems is the size of the payment bundle.

MR. HACKBARTH: So the new technology on the outpatient side is proportionately much larger relative to the base payment, if you will.

DR. BRAUN: The beneficiary's coinsurance is paid on the APC groups and I had a question as to whether they also pay coinsurance on the pass-through codes.

DR. WORZALA: No.

DR. BRAUN: So knowing that, maybe we need to also have a column here on the burden on beneficiaries because that will vary depending on what decision we make.

MR. DEBUSK: Going back and looking from the APC code, I guess August of last year, and we come out with these C codes which were the payment codes for the devices, when they first got into that I think what happened -- and correct me if I'm wrong here -- but as they got into the C codes and trying to balance what was proper payment on an outpatient basis I think they went back and pulled out some of the devices that were already in the bundle and starting paying for them separate as well.

But here's my fear in going forward. Supposing we take 2003, the cutoff date, and we say, all this is rolling back the device cost. We're going to assess this, look at this, roll it all back into the APC code payment comparable to the DRG type structure and then you're going to go forward. From that, as you go forward with new products, new technologies, substantially improved technologies, where a hospital really gets hurt at is some of these devices -- and let me give you an example.

Like there's a new stent out on the marketplace now that's got a zero restenosis. It's a treated stent. The price goes from something like $1,100 to $1,900 and use approximately two of them per procedure. It don't take long to do the math to see what that's going to cost.

If a hospital is in a situation where a cardiologist -- what's going to happen. You bet your life he's going to use those products on his patient. We'd certainly want it used on us. But there's a gap of time in there before CMS recognizes that. Therein lies an area where, if we're not careful, we dig our hospital a new hole right there. And it's an expensive one.

So if we could put together a mechanism where this new technology could be recognized in a short period of time, or there could be some retroactive payments for this, but retroactive payments is something that's not been done in the past. So therein lies a major issue, can we put something together to address that need.

DR. NEWHOUSE: I think this chapter, and to some degree our discussion here, raises a much more general issue for Medicare. The issue is a device or drug, if it's a covered service, that has a high Medicare share -- that is, from the manufacturer's point of view most of the market is Medicare -- and that has a non-trivial amount of spending associated with it. An example of that would have been EPO when it first came out. It was mostly for dialysis patients, and as we just heard $250 million in spending initially.

Now the problem is, if we have a pass-through or if we have the DRG type system for that matter, whatever price the manufacturer names is reimbursed under the pass-through and ultimately rolls into the weight under the DRG system and gets reimbursed. So the manufacturer's incentive is to price very high.

Where I come out here is that there's little alternative for HCFA in this kind of case other than a fee schedule. A fee schedule also does potentially help with the lag issue, if you can get the code out fast enough and the reimbursement there fast enough because it starts to reimburse right away. It doesn't have the roll-in kind of problem that we have with the DRG. But that's I think a side issue.

I think the larger issue, and it goes beyond the pass-through system in the outpatient system, is how Medicare should deal with products that, as I say have a high -- where Medicare is most of the market and they're used fairly widely so that there's a fair amount of spending on them.

MR. SMITH: I want to re-urge something that Bob mentioned yesterday. I found myself wishing in this chapter for some sense of magnitude. What were we talking about both in dollar terms and as a share of outpatient spending. Murray, just more generally that kind of information I think would help.

I want to follow up on something Ralph raised, in a slightly different way. Dan, the financial incentive under the phase-out option suggests that the result would be the avoidance of high-priced new technology. I think we can infer that a corollary to that would be slower diffusion of new technology, particularly in a market like the one Joe just described where we had a Medicare-intensive or Medicare-heavy market, the financial incentive was to avoid the use. I think the logical implication would be that diffusion would be slower than it otherwise would; that is the kind of clinical implications that Ralph raised.

As I read the chapter and went back and read the material for the last meeting, which unfortunately I wasn't at, I didn't find material that helped me grapple with that question. What's

the right price that we ought to pay in order to encourage diffusion? Or what's the price that we end up paying in patient care for artificially slower -- for slowing down diffusion whether artificially or not? I find it hard to think through these options without some ability to grapple with those questions, and the related ones that Ralph raised a while ago.

DR. ZABINSKI: Just one thought on diffusion. Maybe some of the physicians on the Commission can help me out. It's not clear to me that any sort of additional payment is necessary at all to get diffusion. It's the physician who makes the decision, at least as far as I can tell, on what technology to use. Whether an additional payment such as a pass-through is necessary to get the physician to use it, or perhaps to avoid using it, I'm not sure if that really makes much of a difference.

MR. SMITH: But, Dan, if that's true, and I'd like to hear from the clinicians, but then the assertion that phasing out the pass-through would avoid the use of high cost new technology, which has some implication that clinical judgments are overridden by price judgments, that that wouldn't be true? I think both things can't not be true.

If you're right that phasing out the pass-through would cause an avoidance of the use, that's got to slow down diffusion. Now maybe that's not a bad thing in some cases where we've simply got an artificially high-priced technology. But without being able to get past the price questions I think it's very hard to answer the question of what pricing scheme is of most benefit to beneficiaries, which somehow is absent from this conversation.

DR. ROWE: My view, Dan, would be that -- and maybe I'm Pollyanna here -- I think physicians use these new technologies when they can be helpful to their patients. You know, you see laparoscopic cholecystectomy, bam, it diffused immediately, and the use of stents, endovascular approaches to what used to be major vascular surgical procedures, very rapid dissemination throughout the marketplace.

And competition between and among physicians to learn how to use these new technologies, because in fact they've been treating a given disease all their career and here's a new, more effective approach to treating that disease. I don't think that any of them would pass a test on what a pass-through payment is.

DR. NELSON: Only if the hospital stocks it. If you're talking about an artificial joint or whatever, it's only if the hospital is stocking. They can't use it if they can't get it approved to be --

DR. ROWE: Right. But my experience, Alan, is that -- and some of these things are very expensive, as you know -- is that

what the hospitals usually do is they don't avoid stocking these things because they don't want to be a loser in the marketplace either of saying, you know, some hospital starts advertising that you can get the new thing at their hospital and you can't get it across the street.

What the hospitals do do though, on the other hand, is if there's 10 neurosurgeons, they have 11 opinions about what kind of clip they want to use. Or if there's 10 orthopods, they have 11 opinions about which kind of artificial hip they want to use. And they force them to focus on one or two options so they can have some purchasing power. I think the hospitals do do that. But they generally don't avoid purchasing the things at all. That's my experience.

MR. HACKBARTH: Does it follow from that then that option three, phasing out the pass-through, may not pose much of a risk to diffusion?

DR. ROWE: I'd be interested in Ralph's experience, whether it's the same.

MR. HACKBARTH: Certainly it's a simpler system.

MR. MULLER: My sense is, like Jack's, that by and large these judgments get made pretty instantaneously by physicians trying to do the right thing for their patients.

I think part of the reason we're discussing this issue today is there's a major mismatch between thinking you can spend 2.5 percent, which I'm sure was just arbitrarily done, and spending 13, which therefore causes, as it feeds back into the system, kind of untoward effects. My guess is we would not be having this lengthy discussion if the pass-throughs came in at 2.7 rather than 2.5. So I think part of describing this is not just the discussion of the diffusion of technology but also just, in that sense, a retrospective misestimate as to how big this would be.

To answer your question about with option three, avoiding it altogether, I think at the margin some technologies would therefore be limited. I still think the overarching trend would be to introduce the new technologies and try to figure out somewhere down the road as to how to get paid for them. I think very few settings inside the country really limit on a real time basis introduction of a new technology.

There's some places in which it's more possible, like drug formularies, just because this is required, and other places where it's a lot less possible like devices and so forth, where there's considerable decentralization of those kinds of decisions in all settings. So I think there's variance in -- drugs a little harder to introduce because of the regulation of drugs.

Other things are much easier to introduce.

But I would just like to second Joe's sense that the mismatch between two and 13 just on the surface bothers me. I'm not saying that 2.5 was right, but that's what was in the legislation. So I think moving more towards a fee schedule is something that I would support in the sense that that might dampen some of that mismatch, especially as it rolls in a year and-a-half or so down the line into the reweighting of the APCs. So I think that would be a good option to extend.

Obviously, we put in the middle column something else that's a very high burden on CMS and we've had discussions over the fall about how many burdens we put on CMS would be a point of caution on that. It's just one more thing that they couldn't do in time.

I think going on, that's also informing this discussion, is what Chantal referred to earlier, these provisions on outpatient payment may or may not be delayed on January 1st. I think all providers are very concerned that the system is going to be fraught with a lot of complexity, not just between now and April, but for now for a long time forward. CMS has not, and understandably so, has not been able to implement this system. It's like to

have a lot of problems even when they implement.

So I think my concern about a fee schedule therefore, it would be one more burden in the outpatient system that is already overburdened in complexity.

MR. HACKBARTH: Just a clarification. My understanding of option two is that the new technology stays forever outside the APCs, and it's just unbundled, if you will, and paid on a fee schedule basis.

DR. ZABINSKI: That's right, yes.

DR. NEWHOUSE: It could roll into the APCs. The issue is really what it's going to do to the relative weight once it rolls in.

MR. HACKBARTH: That's not how I understood the option.

DR. ZABINSKI: The idea is, option one is just simply setting some sort of national rate for pass-through technology, and option two is to take all technology outside of the outpatient PPS and pay for it on a fee schedule.

MR. HACKBARTH: So under option one you could have payment on what is in essence a fee schedule on a temporary basis and then it's ultimately folded in. Under option two, what makes it distinct from option one is that it stays forever outside the APCs and is paid on a fee schedule.

DR. ZABINSKI: That's correct.

MR. HACKBARTH: It sounds like what you're arguing for is a

variation on option one.

DR. NEWHOUSE: No, I'm really arguing -- there's a difficult to set rates language up there in option one and two. It is difficult to set rates but it may be an unavoidable period for the whole -- that is, there's some conditions where it just may be necessary. We in effect set a rate for EPO, and we agree on a price for EPO.

MR. HACKBARTH: We have some confusion about the basic options and further discussion without clarifying that I think is just going to confuse things. Would it be helpful to actually put the recommendations up? Do they have language that would clarify this for us?

DR. WORZALA: You can do that if you like.

MR. HACKBARTH: But you don't think it will help.

DR. WORZALA: The two differences between one and two is that one is really just covering new technology and it's meant to maintain limited eligibility. Number two covers all technology and is meant to be permanent.

DR. REISCHAUER: How much of total payments is going to be technology?

DR. NEWHOUSE: Can't be all.

DR. REISCHAUER: That's reassuring.

DR. ZABINSKI: If you want to go to the recommendations that might be a good idea.

DR. REISCHAUER: David raised the issue that I wanted to talk about, but I was fascinated by the discussion that then took place and the considered opinion of experts in this area is that the hypothesis that has usually driven, at least politically, these pass-throughs, which is if we don't have something like this we are denying the latest benefits to patients, doesn't seem to be shared by those who would seem to know here. If that's the case, I think we should say it. That there isn't a lot of evidence that that is.

There's a justification one can make which has to do with margins of providers, that you want to make sure that they're paid for what they're doing. But that's very different from how this has been portrayed in the political debate.

DR. NEWHOUSE: There was an example, Bob, of the cochlear implants in the late '80s when HCFA -- this was on your watch -- when HCFA basically lumped them in with a given DRG, didn't cover the cost, and 3M withdrew the product. It's come back on the market since or some version of it. There can be an effect.

DR. NELSON: We aren't in agreement, unanimously.

DR. STOWERS: That's what I was going to speak to. Not to disagree with my learned colleagues, but in the larger urban

center, the stronger hospitals, yes, I think you're right. I think regardless of what size hospital you're in the physicians try to do what's best for their patient and get the technology to them as quick as possible.

But if you get in the smaller urban hospitals or in the rural hospitals that are struggling or having more financial problems, it becomes a much closer relationship between the decisionmaking and the financial difficulty of the hospital. There can be a delaying of those technologies being brought in, and we've seen many, many examples of that, until it's financially feasible for the hospital to do that.

So I think just to make a blanket statement that across the country there's no delay in technology. I have to agree entirely here that there is a tremendous timeliness issue of getting these technologies reimbursed. So I'm really worried and that's what I wanted to speak to, is that we just leave that blanket impression that there's absolute access.

MR. HACKBARTH: Floyd, and then we ought to turn to the two recommendations.

DR. LOOP: I don't know how practical option two is to create a fee schedule for all science and technology. I think you're asking an agency that can't get done what's supposed to be done, to do something that's a momentous undertaking, is impractical.

On option three, I thought that contained the understatement of the year: the potential disadvantage is that base rates may not adequately cover the high cost of new technology. For sure it probably wouldn't. I think then you run the risk of retarding the diffusion of good technology. I don't think we know the unintended consequences of phasing out all the pass-through payments.

MR. DEBUSK: Keep in mind with option two there, that coding system is already in place. So CMS does not have that big a challenge there, if you choose to break it out, Joe. It is in place, the C coding system.

DR. NEWHOUSE: To be clear, I would take a subset. I think all technology is a straw man.

MR. HACKBARTH: Do you want to put up the recommendations? By the way, this is not an issue that we're going to resolve today. This will come back in January.

DR. ZABINSKI: Under option one, the recommendation we would offer would be, the Congress should replace hospital-specific payments for all pass-through devices with national payment rates that reflect hospitals' acquisition costs. The Congress also should replace payments for pass-through drugs and biologicals

based on average wholesale price with national payment rates that reflect hospitals' acquisition costs.

Should I go on to the next option?

For the second option, that's a fee schedule for all technology. We have, all drugs, biologicals, and medical devices, both pass-through and non-pass-through, should be removed from the outpatient PPS and paid under a fee schedule that reflects hospitals' acquisition costs.

And the third option, the phase-out, would be, pass-through payments should be phased out so that all technologies are paid through base payment rates in the outpatient PPS.

MR. HACKBARTH: A question about number one. In our comment letter on the regulation, one of the problems we identified was that the mechanism created incentives to jack up charges. So that's one issue that we address in option one. But other problems were also identified. I'm not sure that we're addressing all the points that raised in that letter. Frankly I'm blanking right now on all the issues that we did bring up, but I know this wasn't the only point.

So if we're going to have a modified pass-through, I'm raising the question of whether there are other problems that need to be addressed in the pass-through approach.

DR. ZABINSKI: I'm not completely recalling effectively either, even though I wrote the letter, but I think a lot of it was due to -- we pointed out that, first of all they set this 2.5 percent cap. But then Congress turned around and allowed all sorts of additional --

MR. HACKBARTH: Right.

DR. ZABINSKI: But I think that a lot of people liken this to a snake swallowing rat and the rat has to pass its way through the snake. The idea is that you have a lot of these pass-through items right now and that caused an exceedingly large disparity between the 2.5 percent limit and the actual payments.

But the idea is that in the future it's really expected -- Chantal talked to somebody that represents the device industry and I also think somebody from CMS and they both said that they really expect a very small number, at least a relatively small number of pass-through items into the future. So I think this 2.5 percent limit, even if it's exceeded, it won't be exceeded by a very wide margin. Chantal can correct me on that.

MR. HACKBARTH: You find that credible? I've heard people make that point, that this was a temporary problem.

DR. WORZALA: Yes, that seems to be consensus.

MR. MULLER: Why do we choose so broadly, to go back to Joe's point. We have in the pass-through a limited set of

devices that, as Dan said, got expanded a bit. But why expand 100 percent. We want to keep this for new, important technology rather than --

DR. ZABINSKI: It wouldn't be additional payments for the old technology. It would just be setting a rate that's appropriate for the old technology. There wouldn't be any sort of pass-through payment for it.

MR. MULLER: No, but I'm saying is that when you say all drug, biologicals, and medical devices, most of those are supposedly carried inside the APC system, so why do you want to take them back out?

DR. WORZALA: That rationale would just be to limit the disparity in how payments are made for complements, things that you could choose between one versus the other, and one is paid one way and one is paid another way. The notion is that you get rid of that disparity which tends to give an incentive to provide services using pass-through items as opposed to items bundled.

MR. MULLER: But my suggestion is, and it's in some way -- the way two is now stated I don't like it as much as I did before when I said that. Hadn't read it then.

The question we have is how to get the appropriate diffusion of new technology without having excessive cost be allowed in that system that skews the overall outpatient payment system in a way that gets APCs reweighted in inappropriate ways, and transfers going on. So to me, trying to have both an incentive for the diffusion of technology without excessive margins to be made and skewing to go on is what we're trying to figure out here.

So that strikes me that somewhere between one or two that allows, as Joe has indicated, some fee schedule for a limited number of these new technologies -- not 100 percent, and not 100 percent of devices, drugs, and so forth, and to remove the incentive -- to remove whatever -- you know, if the reason we went from 2.5 to 13 is that the list got too big as opposed to the price got too high -- and I'd like to hear your judgment on that -- that's a different matter.

MR. HACKBARTH: It really sounds to me, Ralph, like you are arguing for option one.

DR. NEWHOUSE: Some combination of one and two.

MR. MULLER: Yes, some combination of one and two.

MR. HACKBARTH: Basically two says that we pay on a fee schedule, and option one also includes that we pay on something like a fee schedule.

DR. ROWE: No, it's acquisition cost. So if you spend $40,000 for a stent; fine, the hospital pays and we pay $40,000.

That's not a fee schedule. The fee schedule is being determined by the manufacturer in that case.

MR. HACKBARTH: Although if you move away from hospital-specific cost-to-charge ratios and go to nationals you can dampen that incentive and you have a fee schedule --

DR. NEWHOUSE: Why? It's still there. Everybody faces the same cost from the manufacturer.

DR. ROWE: Yes, it's a single source producer and he's going to charge everybody the same rate. What we'd like to say is what Medicare is going to purchaser -- it's a large purchaser and they're going to pay --

DR. NEWHOUSE: It's not the hospital's charge. It's the manufacturer's.

MR. HACKBARTH: So let me just continue trying to get clarification. So what you're saying is in option 1A that involves a pass-through for a separate payment for new technology, and let's not go back to the all the old stuff and put it on a fee schedule. But when we have the new stuff that it's a fee schedule as opposed the current mechanism.

DR. NEWHOUSE: If it's a big Medicare share and if it's enough cost, that's how I would segregate. I agree with Floyd that we can't take on everything.

MS. RAPHAEL: I just have one point of clarification. I feel in this realm do-ability is very important. We have to decide what to cover, how much to pay, and you want to do it with some rapidity so that you can get this into the hands of whoever is practicing patient care. I'm not entire clear on the fee schedule proposal, whether it's doable and I'd like to better understand that.

Because if this is, even if we think of it as an interim solution on the way to getting better data and being able to put it into the base rates, an interim solution should be something you could do fairly soon. I just would like from those of you who are more familiar with this, to get a sense of whether or not this is in fact doable.

DR. NEWHOUSE: My problem isn't an interim problem, it's an ongoing problem.

MS. RAPHAEL: So you would never fold it into the base rates.

DR. NEWHOUSE: The issue is what price goes into the base rate and who determines it. As Jack said, in the particular case of products I'm concerned about you essentially have the manufacturer determining the base rate.

MS. RAPHAEL: But you can do that differently. I thought you could use the fee schedule on the road to having more

accurate data for the base rate.

MR. MULLER: I agree with your argument, if a fee schedule takes 24 months to develop and until you develop it you can't do any of this access to technology then that would be, to me, kind of don't do it that way. Because the point is to get the diffusion of technology. I concede if it takes CMS in the scale of all the multiple things they have to do, so much time to get the fee schedule, that would be an argument against using the fee schedule.

MR. HACKBARTH: We're not going to resolve this today but I think we've identified a clear question that would be helpful to have some more thinking about. It's not a clear question to you, Dan, so why don't you --

DR. ZABINSKI: Yes, I'm a little -- to me, option one, I still get the idea that what Ralph is talking about is a somewhat focused special payment for what, new technology?

MR. MULLER: Selected new technology, in a real outlier context.

MR. HACKBARTH: So it's higher than some percentage of -- I'm not sure what. But it's expensive new technology that you're worried about.

DR. ROSS: So if you set a high enough price for it you move yourself into the pass-through category?

I think part of what I hear from commissioners is almost a belief system which is that if you believe that everything is guided by clinical decisions I think that actually drives you to option three; sort of, declare victory, quit worrying about it. If you think financial incentives are extremely important then you go to one or two, and that starts to get mostly to operational questions at that stage.

MR. MULLER: I think I would agree with Ray's point. I'm not saying that financial decisions never make any difference. Obviously, when one starts putting in prosthesis that cost $20,000 and five stents at $2,000 a pop and the procedure gets reimbursed $1,100 you start saying, just the stents themselves are $10,000. So people do make those kind of judgments. I don't want to deny that. But I think, on the other hand, in that kind of example if something costs $1,500 versus $1,100 -- everybody picks their spots as to where you make -- where you try to intervene.

I'm just saying, one does not want to really dampen -- and the examples that Jack gave are overall savings to the system. When you look at the whole system there, having people with laparoscopic surgery and not being admitted and so forth are overall savings. So in that sense you want the stuff out there

to save overall. You can't just look at it in that kind of narrow way.

So my point is just to Dan, a more limited set that has some kind of threshold task -- not all. And if it's feasible, I fully concede to Carol's comment; if it takes forever to get the fee schedule going then that's kind of an argument against the fee schedule.

MR. SMITH: Ralph, let me make sure I understand. What you'd argue for at the moment is option one modified by some threshold, some price or price increment threshold, and changing from acquisition cost to a fee schedule.

MR. PETTENGILL: It's really important to remember that we got here because we don't know. We have a pass-through that was enacted because CMS doesn't get the data to include it in the APC relative weights. If they had the data, then this whole problem would be moot. So the question really is, how can you construct something that will work in the interim when you don't have the data to begin with? That's the question.

DR. NEWHOUSE: I think, to reiterate what Murray said, I think the ultimate -- I don't think the issue is a transition problem. I think the ultimate issue where I would come down, if the clinicians are right than option three is clearly better. And if financial considerations are important then I would have said, as Ralph did, some combination of one and two where you go to two in those cases where it's a high Medicare share and there's a non-trivial amount of spending. So there's some trigger that puts you into a fee schedule as in the erythropoietin example.

MR. SMITH: Just one comment. From this side of table -- and Carol unfortunately isn't here -- but we thought we heard the clinicians speak with more than one voice. At least part of what I heard was a big city voice and a not-so-big city voice.

DR. WORZALA: Can I just make one -- I'm sorry to do this, Glenn. I never answered Ralph's question about whether it was price or volume that took the 2.5 percent to 13 percent. The answer is both, but volume played a bigger role. Going forward, as we stated before, volume should play less of a role. We focused on price because we thought that the volume issue and the eligibility criteria were moving in the right direction, becoming more selective, and that the key remaining problem was how the price was set.

Apparently we didn't give you enough background on that sort of thing, so for January I'll give a much better description of the eligibility and how things are moving in that realm.

DR. NEWHOUSE: Chantal, with all respect, I don't think

Ralph's question can be answered because the price that is set is not independent of the reimbursement methods. Therefore one would have to ask, what would the price have been under some alternative that wasn't this system, and I don't see how we could have known that.

MR. HACKBARTH: We need to move on. 147